MAY 2 4 2012

510(k) SUMMARY

The following 510(k) summary is being submitted as required by 21 CFR 807.92(a):

1.

Submitter:	L&K BIOMED Co., Ltd. #1104, Ace High-end Tower 3 cha, 371-50, Gasan-Dong, Geumcheon-gu, Seoul 153-803 Republic of Korea
Contact Person:	KiHyang Kim Phone. 82-2-2624-1475 FAX .82-2-2624-1477 E-mail: khkim@lnkbiomed.com
Date Prepared	April 30, 2012

2. Device Identification

Trade Name	LEXUS Cervical Intervertebral body Fusion Cage System
Common Name	Intervertebral Body Fusion Device
Classification Name	intervertebral fusion device with bone graft, cervical
Regulation Number	21 CFR 888.3080
Regulatory Class	Class II
Product Code	ODP

3. Predicate or Legally Marketed Devices which are Substantially Equivalent

The design feature and indications for use for the subject LEXUS Cervical Intervertebral body Fusion Cage System is substantially equivalent to the following predicates:

- **LDR Spine**: LDR Spine Cervical Interbody Fusion System (K091088,K113559)
- **Spine Art**: TRYPTIK CA Anterior Intersomatic Cervical Cage (K091873)
- **Advanced Medical Technologies AG**: SHELL Cages (K080401)
- **Globus Medical Inc.**: COALITION ™ Spacer (K083389)

4. Description of the Device

LEXUS Cervical Intervertebral body Fusion Cage System intended for use as an interbody fusion cage device and must be used with supplemental fixation. The devices are available in a variety of different sizes and configurations to accommodate anatomical variation in different vertebral levels and/or patient anatomy. The devices are made of PEEK-OPTIMA® LTI with marker pins made of titanium alloy (Ti-6Al-4V ELI).

5. Indications for Use

LEXUS Cervical Intervertebral body Fusion Cage System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. LEXUS Cervical Intervertebral body Fusion Cage System is used to facilitate intervertebral body fusion in the cervical spine at the C3 to C7 disc levels using autograft bone. LEXUS Cervical Intervertebral body Fusion Cage System is to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

6. Discussion of the Non-clinical Testing

The LEXUS Cervical Intervertebral body Fusion Cage devices were tested according to the ASTM F 2077, specifically, Static and Dynamic Axial Compression, Static and Dynamic Compression-Shear Testing, Static and Dynamic Torsion Testing, Expulsion Testing and Static Subsidence testing under Axial Compression, per ASTM F 2267.

7. Summary of Technology Characteristics

The LEXUS Cervical Intervertebral body Fusion Cage System shares technological characteristics similar to the predicate devices. These characteristics include similar design, the same materials and the same intended use.

8. Conclusion

The LEXUS Cervical Intervertebral body Fusion Cage System is substantially equivalent to the device referenced above and is therefore safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

L&K Biomed Co., Ltd.
% Ms. Ki Hyang Kim
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MAY 2 4 2012

Re: K120840
Trade/Device Name: LEXUS Cervical Intervertebral Body Fusion Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: May 3, 2012
Received: May 4, 2012

Dear Ms. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):

Device Name: LEXUS Cervical Intervertebral body Fusion Cage System

Indications For Use:

LEXUS Cervical Intervertebral body Fusion Cage System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. LEXUS Cervical Intervertebral body Fusion Cage System is used to facilitate intervertebral body fusion in the cervical spine at the C3 to C7 disc levels using autograft bone. LEXUS Cervical Intervertebral body Fusion Cage System is to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____

(Part 21 CER801 Subpart D) (21 CER801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (OED)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120840